

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE LITIGATION

THIS DOCUMENT RELATES TO:

The City of New York v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 04-CV-06054

County of Albany v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0425

County of Allegany v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-0236

County of Broome v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0456

County of Cattaraugus v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-0256

County of Cayuga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0423

County of Chautauqua v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-0214

County of Chemung v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6744

County of Chenango v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0354

County of Columbia v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0867

County of Cortland v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0881

County of Dutchess v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 05-CV-6458

County of Essex v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0878

County of Fulton v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0519

MDL NO. 1456
Civil Action No. 01-12257-PBS

Judge Patti B. Saris

**PLAINTIFFS' OPPOSITION TO
BIOGEN IDEC INC.'S
SEPARATE MEMORANDUM
OF LAW IN SUPPORT OF
MOTION TO DISMISS**

County of Genesee v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-00267

County of Greene v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0474

County of Herkimer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00415

County of Jefferson v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0715

County of Lewis v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0839

County of Madison v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00714

County of Monroe v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6148

County of Nassau v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 04-CV-05126

County of Niagara v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06296

County of Oneida v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0489

County of Onondaga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0088

County of Ontario v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6373

County of Orleans v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6371

County of Putnam v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 05-CV-04740

County of Rensselaer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00422

County of Rockland v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-7055

County of Schuyler v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6387

County of Seneca v. Abbott Laboratories, Inc., et al.

W.D.N.Y. Case No. 05-CV-6370

County of St. Lawrence v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0479

County of Saratoga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0478

County of Steuben v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6223

County of Suffolk v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 03-CV-12257

County of Tompkins v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0397

County of Ulster v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 06-CV-0123

County of Warren v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0468

County of Washington v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0408

County of Wayne v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06138

County of Westchester v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-6178

County of Wyoming v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6379

County of Yates v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06172

INTRODUCTION

Biogen Idec Inc.'s ("Biogen") individual memorandum (hereinafter "Biogen MTD") seeks the dismissal of claims relating to its products Avonex, Amevive and Zevalin. With regard to Amevive and Zevalin, Biogen asserts that plaintiffs did not allege that they paid for the drugs. With regard to Avonex, Biogen argues that plaintiffs' claims are not pled with sufficient particularity to satisfy Fed. R. Civ. P. 8(a) and 9(b) because: (i) plaintiffs did not plead how it determined the fraudulent AWP to support its AWP based claims; and, (ii) plaintiffs did not plead a specific fraudulent Best Price and relied upon statements by a former employee in an employment discrimination suit to support their Best Price based claims. Biogen also contends that the Court dismissed all claims against it in the Suffolk matter.¹

First, plaintiffs' claims regarding Avonex, meet the particularity requirements of Fed. R. Civ. P. 8(b) and 9(b) as well as the Court's prior rulings, including *County of Suffolk v. Abbott Labs., et al.*² Second, the Court did not dismiss Suffolk's AWP unjust enrichment claims or its claim for violation of N.Y.C.R.R. 515.2(b)(4) and (5) against Biogen. Accordingly, Biogen's motion should be denied for this drug.

DISCUSSION

A. Plaintiffs' Best Price Claims Relating to Avonex Should Be Sustained.

Biogen claims plaintiffs do not allege particular facts for their purchases of Avonex in support of their Best Price claims and as such all Avonex Best Price claims should be dismissed under Fed. R. Civ. P. 9(b). This is false.

¹ Plaintiffs previously did not in fact pay for Amevive or Zevalin and so withdraw their claims with respect to these drugs.

² See *In re Pharm. Indus. Average Wholesale Price Litig.* 339 F.Supp.2d 165, 173 ("Suffolk I"); *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257 2004 WL 2387125 at *3 (D. Mass., Oct. 26, 2004) ("Suffolk II"); *In re Pharm. Indus. Average Wholesale Price Litig.* Memorandum and Order at 1-2 (D. Mass. April 8, 2005) ("Suffolk III"). All other causes are addressed in Plaintiffs Consolidated Opposition to Defendants' Motion to Dismiss, filed contemporaneously herewith (referred to herein as "Consolidated MTD Opposition").

In order to maintain a Best Price claim, plaintiffs must “set forth minimal facts with respect to (1) the allegedly fraudulent or false price reported to the state for any specific drug; or (2) any information showing a company-wide scheme to misstate Best Prices.” *Suffolk II*, 2004 WL 2387125, at *3.

Plaintiffs did both. First, plaintiffs assert Best Price claims for purchases of Avonex. *See* CC ¶ 335; NSAC Exh. B. Second, plaintiffs allege a company-wide scheme and strategy whereby Biogen actively utilized free sample and off-invoice pricing to lower prices and maximize sales. *See* CC at ¶ 333. Plaintiffs also allege off-invoice pricing allows a manufacturer to lower the net cost to the purchaser while concealing the actual cost beneath the fiction of a higher invoice. *See* CC at ¶ 153; NSAC ¶ 122.

Furthermore, plaintiffs allege that: (1) Biogen engaged in a practice of providing large amounts of free samples to physicians with full knowledge that the physicians were seeking Medicaid reimbursement or charging customers for the free samples, and did not include the free samples in its calculation of Best Price (CC at ¶ 335); (2) Biogen gave its sales force incentives and discretion to provide free samples to reimburse physicians for losses on past purchases, which were not included in Biogen’s calculation of Best Price or Average Manufacturers Price (*id.* at ¶ 333); (3) when warning of the potential rebate liability, Biogen admonished its Associate Director in the area of Medicare and Medicaid Reimbursement, the source of the warning, who was told to keep amount of free samples distributed confidential (*id.* at ¶ 334); and (4) Biogen utilized off-invoice pricing through inflated credits to provide to Biogen’s largest customer, Cardinal Health, a *de facto* discount or rebate when it returned large quantities of Avonex and received credit at the then current cost of Avonex instead of the lower actual cost of Avonex when originally purchased (*id.* at ¶ 335).

Finally, even if the Court finds that the pleadings have not satisfied Fed. R. Civ. P. 9(b),

plaintiffs' claims relating to Avonex for unjust enrichment and violations of 18 N.Y.C.R.R. §515.2(b)(4) and (5) and should be sustained because the Court has ruled Fed. R. Civ. P. 9(b) does not apply to such claims. *Suffolk II*, 2004 WL 2004 2387125, at *2.

B. Plaintiffs' AWP Claims Against Biogen Relating to Avonex Should Be Sustained

Biogen says that plaintiffs fail to sufficiently plead their Avonex related AWP claims with particularity because plaintiffs: (i) did not adequately describe how it determined the "Fraudulent AWP", and (ii) did not identify a market price or spread. *See* Biogen MTD at 3.

In order to maintain an AWP claim for Avonex, plaintiffs must set forth factual allegations regarding spread, including internal documents or government investigations from which an inference of fraud can reasonably be made. *See Suffolk II*, 2004 WL 2387125, at *2; *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 187, 209 (D. Mass. 2004)(*"Pharm. III"*). In alleging a spread, using a calculated actual average sales price for a drug will not suffice. *See Suffolk III* at *2.

Plaintiffs allege with detail the basis for claiming that Avonex's AWP is fraudulent. Plaintiffs allege that Biogen submits false and inflated wholesale price information in order to engage in marketing the spread; that Biogen provides grossly inflated wholesale pricing information to the publishing services, causing them to publish similarly inflated AWP's; and that Biogen further distorts the wholesale pricing information through the use of discounted contract pricing, up-front rebates, discounts and off-invoice transactions, all of which mask the falseness of its AWP's and WACs. *See* CC ¶¶ 5-20, 153; NSAC ¶¶ 3-14, 122.

Plaintiffs also (1) provide the fraudulent AWP for Avonex;³ (2) allege the fraudulent conduct surrounding the discounted pricing practices of Biogen's Amevive SPA program; (3)

³Plaintiffs did not set forth a particular spread for Avonex products. Plaintiffs now have sufficient Biogen market price data to do so and plaintiffs request leave of Court to provide such spread detail should the Court so require.

discussed the fraudulent conduct of Biogen in provided large amounts of free samples to physicians knowing that the physicians were seeking Medicaid reimbursement for them; (4) discussed the fraudulent conduct regarding the falsely inflated credits for Avonex returns Biogen gave to Cardinal Health (Biogen's largest customer); (5) discussed the fraudulent practices witnessed by the former Biogen Associate Director in the area of Medicare and Medicaid reimbursement; and (6) detailed the company-wide off-invoicing scheme to misstate Biogen's Best Price. *See* CC ¶¶ 328-336, Exh. A; NSAC ¶¶ 307-316, Exh. B.

The foregoing is sufficient to draw a reasonable and decidedly sound inference of a company-wide AWP fraud regarding Biogen products, including Avonex, in compliance with the requirements of Fed. R. Civ. P. 9(b). *See U.S. ex rel Franklin v. Parke Davis*, 147 F.Supp.2d 39, 49 (D.Mass 2001)(Saris, J.)("[W]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible.")

Finally, Biogen does not contest plaintiffs' AWP unjust enrichment claims, and AWP claims for violation of 18 N.Y.C.R.R. §515.2(b)(4) & (5). The Court ruled that Fed. R. Civ. P. 9(b) does not apply to such claims. *Suffolk II*, 2004 WL 2387125, at *2. Accordingly, Plaintiffs' AWP claims relating to Avonex should be sustained.

C. The Court Previously Sustained Certain Suffolk Claims Against Biogen.

Biogen states that "the Court has dismissed all claims asserted by Suffolk County." MTD at 1. For the reasons set forth in the Procedural History Section of the consolidated MTD Opposition, this is incorrect. *See* Consolidated MTD Opposition. The April 8, 2005 ruling ("*Suffolk III*") (regarding whether Suffolk satisfied 9(b) in respect to the Suffolk 13 +6) in no way modified either the *Suffolk I* or the *Suffolk II* decisions. These decisions sustained Suffolk's unjust enrichment AWP claim against the Suffolk 13 +6 and sustained Suffolk's claim for violation of N.Y.C.R.R. §515.2 (b)(4) and (5). In *Suffolk II*, the court expressly held that Rule

9(b) did not apply to these claims, as they “do not require a pleading of fraud or mistake.”
Suffolk II, 2004 WL 2387125, at *2.

CONCLUSION

For all the foregoing reasons, Biogen’s Motion to Dismiss should be denied in its entirety as to the drug Avonex.

Dated: April 17, 2006

Respectfully submitted,

**City of New York and all captioned Counties
except Nassau, by**

KIRBY McINERNEY & SQUIRE, LLP
830 Third Avenue
New York, New York 10022
(212) 371-6600

/s/ Joanne M. Cicala
Joanne M. Cicala (JC 5032)
James P. Carroll Jr. (JPC 8348)
Aaron D. Hovan (AH 3290)
David E. Kovel (DK 4760) (*pro hac vice*
application pending)

For the City of New York

MICHAEL A. CARDOZO
Corporation Counsel of the
City of New York

John R. Low-Beer (JL 3755)
Richard J. Costa (RC 7278)
Assistant Corporation Counsels
100 Church Street, Room 3-162
New York, New York 10007
(212) 788-1007

LORNA B. GOODMAN

Peter J. Clines
Rachel S. Paster
Nassau County Attorney, by

MOULTON & GANS, P.C.

/s/ Nancy Freeman Gans

Nancy Freeman Gans, BBO # 184540

55 Cleveland Road
Wellesley, MA 02481
Telephone: (781) 235-2246
Facsimile: (781) 239-0353

**MILBERG WEISS BERSHAD
& SCHULMAN LLP**

Melvyn I. Weiss
Michael M. Buchman
Ryan G. Kriger
One Pennsylvania Plaza
New York, New York 10119-0165
Telephone: (212) 594-5300
Facsimile: (212) 868-1229

*Special Counsel for the
County of Nassau*